IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ABBOTT LABORATORIES, an Illinois corporation, FOURNIER INDUSTRIE ET SANTÉ, a French corporation, and LABORATOIRES FOURNIER S.A., a French corporation, Plaintiffs, v. TEVA PHARMACEUTICALS USA, Inc., a Delaware corporation, Defendant.	Civil Action No. 02-1512 (KAJ) (consolidated)
TEVA PHARMACEUTICALS USA, Inc., a Delaware corporation, and TEVA PHARMACEUTICAL INDUSTRIES LTD., an Israeli corporation, Counterclaim Plaintiffs, v. ABBOTT LABORATORIES, an Illinois corporation, FOURNIER INDUSTRIE ET SANTÉ, a French corporation, and LABORATOIRES FOURNIER, S.A., a French corporation, Counterclaim Defendants.	
ABBOTT LABORATORIES, an Illinois corporation, FOURNIER INDUSTRIE ET SANTÉ, a French corporation, and LABORATOIRES FOURNIER S.A., a French corporation, Plaintiffs, v. IMPAX LABORATORIES, INC, a Delaware corporation, Defendant.	Civil Action No.: 03-120-KAJ (Consolidated)

IMPAX LABORATORIES, INC, a Delaware corporation, Counterclaim Plaintiffs, v. ABBOTT LABORATORIES, an Illinois corporation, FOURNIER INDUSTRIE ET SANTÉ, a French corporation, and LABORATOIRES FOURNIER, S.A., a French corporation, Counterclaim Defendants.	
IN RE TRICOR DIRECT PURCHASER ANTITRUST LITIGATION THIS DOCUMENT RELATES TO: ALL ACTIONS	Civil Action No. 05-340 (KAJ) (consolidated)
IN RE TRICOR INDIRECT PURCHASER ANTITRUST LITIGATION THIS DOCUMENT RELATES TO: ALL ACTIONS	Civil Action No. 05-360 (KAJ) (consolidated)

DEFENDANTS' CONSOLIDATED REPLY BRIEF IN SUPPORT OF THEIR CONSOLIDATED MOTION TO DISMISS PLAINTIFFS' COMPLAINTS

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INTRODUCTION

Plaintiffs turn antitrust law on its head. The antitrust laws are designed to ensure vigorous competition by encouraging firms to introduce better products to gain a competitive advantage in the marketplace. This is what Abbott and Fournier have done as they have introduced new products to better compete against generics and the array of anti-Dyslipidemia drugs on the market, including Lipitor, Zocor, Pravachol and Crestor. The effect of this continued innovation, Plaintiffs admit, is that Teva and Impax were always one step behind. While nothing prevented Teva or Impax from selling a fenofibrate product, Plaintiffs allege that Abbott and Fournier violated the antitrust laws because their continued innovation made it more difficult for Teva and Impax to follow their business model of free-riding. What Plaintiffs are asking for is not the ability to compete fairly, but for a right to compete only on their own terms, without the need to develop innovative products, to engage in product promotion, or even to hire a sales force. The antitrust laws protect competition, not competitors. Nothing in the Hatch-Waxman Act ("Hatch-Waxman") disturbs this principle.

Plaintiffs' claims of litigation misconduct are also devoid of merit. First, they attempt to bypass the requirements of *Walker Process* by taking an affirmative defense under the patent laws – the doctrine of inequitable conduct – and transforming it into a theory of antitrust liability. Plaintiffs next try to dismiss the record in the Tablet Litigations. Yet, this Court can and should take judicial notice of its pretrial rulings. Finally, the Direct Purchaser Plaintiffs dredge up the Capsule Litigations, filed over five years ago, to argue that such litigations were objectively baseless, when Teva and Impax, the actual defendants in that litigation, did not make such a claim then nor do they now.

Plaintiffs' allegations fail to state cognizable claims and therefore must be dismissed.

ARGUMENT

I. PLAINTIFFS' THEORY IS PREMISED ON A MISREADING OF THE HATCH-WAXMAN ACT.

Plaintiffs suggest that Hatch-Waxman somehow provides special rules under the antitrust laws for manufacturers of generic pharmaceuticals. Plaintiffs focus only on selected parts of Hatch-Waxman that discuss facilitating the introduction of generic drugs and claim that anything that does not actively encourage the introduction of generic drugs is at odds with Hatch-Waxman and presumptively anticompetitive.[1]

This is not the first time Plaintiffs have asserted this reasoning. Elsewhere in this Circuit, Teva argued that its status as the marketing partner of another generic manufacturer gave it the right to escape imposition of a preliminary injunction after the court found that there was a likelihood of infringement. *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, No. 05-CV-620 (D.N.J. Mar. 29, 2005) (bench decision). In affirming the district court's injunction, the Federal Circuit rejected the generics' argument that their infringement should be disregarded simply because the Hatch-Waxman framework "makes low cost generic drugs available to the public." *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005). Instead, the court recognized

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[1] *See, e.g.*, Directs Opp. at 48 (alleging that because Hatch-Waxman is "clearly designed to promote price competition by generics – and Defendants' conduct is indisputably designed to have the exact opposite effect – Defendants' . . . rationalizations . . . for their plainly exclusionary conduct must fail"); Indirects Opp. at 14 (referring to the legislative history, cited with *Serono Labs, Inc. v. Shalala*, 158 F.3d 1313, 1316 (D.C. Cir. 1998), for the proposition that Congress' intent in enacting Hatch-Waxman simply was "to make available more low cost generic drugs").

the "exclusionary rights conveyed by pharmaceutical patents" and the "public policy inherent in the patent laws designed to encourage useful inventions." *Id.*[2]

Hatch-Waxman constitutes a careful balancing by Congress of two equally important and competing interests: promotion of brand drug innovations and the development and marketing of non-infringing generics.[3] To satisfy the interests of innovation, Congress provided in Hatch-Waxman a statutory 30-month stay, during which the brand manufacturers could identify and enforce their intellectual property rights. *See* H.R. Rep. 98-857 (II), 1984 U.S.C.C.A.N. 2686 (1984) at 9-10. To satisfy the interests of low-cost drug development, Congress added (i) a mechanism allowing generic manufacturers to rely on the brand manufacturer's safety and efficacy data in support of the generics' abbreviated ANDA approval process (thereby permitting generic manufacturers to reduce their research and development costs), and (ii) a 180-day exclusivity period to the first generic provider that develops a generic product, during which no other generic can market a competing product. *See In re Cardizem Antitrust Litig.*, 332 F.3d 896, 901 (6th Cir. 2003) (describing the 180-day exclusivity period as compensation to the generic manufacturers for the 30-month stay granted to brand manufacturers).

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[2] Teva's litigation stance in the *Pfizer* case is telling. In addition to arguing that the public interest supported their infringement, they also suggested that the patentee had waived the right to an injunction by not availing itself of Hatch-Waxman's 30-month stay. The Federal Circuit rejected this, holding that "there is no requirement that a patent owner take advantage of the statutory carrot of a thirty-month stay, and certainly no statutory stick for choosing not to." 429 F.3d at 1382.

[3] *See, e.g.*, H.R. Rep. 98-857 (II) at 7 (describing Hatch-Waxman as a "compromise between [those] two competing economic interests"); *see also Teva Pharm. Indus. v. Crawford*, 410 F.3d 51, 54 (D.C. Cir. 2005) ("Congress sought to strike a balance between incentives, on the one hand, for innovation, and on the other, for quickly getting lower-cost generic drugs to market"); *Abbott Labs. v. Young*, 920 F.2d 984, 985 (D.C. Cir. 1990) (Hatch-Waxman "created a new system for protecting both the interests of drug manufacturers who produce new drugs and the interests of generic drug manufacturers and their consumers"); *Zenith Labs., Inc. v. Abbott Labs.*, No. 96-1661, 1997 U.S. Dist. LEXIS 23954 at *29 (D.N.J. Oct. 3, 1997) (rejecting plaintiff's argument that the benefits of generic drugs outweigh other interests considered by Hatch-Waxman) (attached hereto as Exhibit 1).

Hatch-Waxman does not relieve generic manufacturers of the burdens of competition. The 30-month stay about which Plaintiffs constantly complain applies only to the specific formulation for which Defendants spent the time and money developing and obtaining regulatory approval. Even during the 30-month stay, Teva and Impax were free to bring any other forms of fenofibrate products to the market – Plaintiffs' claims are no more than that Teva and Impax could not copy Defendants' specific product when and how they would like. By ignoring the full picture, Plaintiffs view Abbott's and Fournier's compliance with the Hatch-Waxman framework as "gaming" the system.[4] Rather than attack Defendants' lawful use of Hatch-Waxman's 30-month stay in this Court, Plaintiffs should take that complaint to Congress. Accordingly, Plaintiffs' reading of Hatch-Waxman is incorrect and does not support their Section 2 claims.

II. PLAINTIFFS APPLY THE WRONG STANDARD TO SAME MARKET PRODUCT INNOVATION WHEN THE CORRECT STANDARD DEMONSTRATES THAT DEFENDANTS' INTRODUCTIONS WERE PROPER.

A. Same Market Innovation Does Not Violate The Antitrust Laws When The New Product Offers Any Improvement Over The Old Form.

Section 2 of the Sherman Act does not handcuff firms with alleged monopoly power and prevent them from competing vigorously against their rivals; a monopolist is free to innovate new products and to fight to keep its customers and its market. *See Goldwasser v.*

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[4] *See, e.g.*, Teva Opp. at 34-35 (alleging stays were unlawful delays of generic entry); Directs Opp. at 6 (claiming stays form part of exclusionary scheme). Ironically, while Plaintiffs uniformly decry the statutory 30-month stays granted Abbott and Fournier as anticompetitive, Teva and Impax have no qualms about obtaining 180-day exclusivity periods preventing other rivals from launching competitive generic products. The FDA website (which is subject to judicial notice in accordance with *In re Wellbutrin SR/Zyban Antitrust Litigation*, 281 F. Supp. 2d 751, 754 n.2 (E.D. Pa. 2003), cited in Directs Opp. at 5 n.3), is replete with such examples. *See, e.g., Position of Teva Pharms. USA Inc. With Respect to 180-day Exclusivity for Mirtazapine 45 mg Tablets*, available at http://www.fda.gov/ohrms/dockets/dailys/03/Jan03/013003/8004d287.doc (discussing Teva's challenge to a Citizens Petition in an attempt to ensure that it would preserve the 180-day exclusivity for its 45 mg mirtazapine product) (attached hereto as Exhibit 2).

Ameritech Corp., 222 F.3d 390, 397 (7th Cir. 2000) ("even a monopolist is entitled to compete; it need not lie down and play dead, as it watches the quality of its products deteriorate and its customers become disaffected").

Only wrongful conduct by a monopolist violates Section 2. Courts have generally found a monopolist's conduct to be wrongful in two circumstances: (1) where the conduct is "economically irrational *but for* the consequences on competition" and (2) where it is otherwise "improper for reasons extrinsic to the antitrust laws." I *Antitrust Law Developments* at 247, 249 (ABA 5th ed. 2002) (emphasis added). Application of these principles to the context of same market product introductions is straightforward. First, Defendants' offering of improved products is not economically irrational, particularly in a broader marketplace in which TriCor is competing with other drugs. When the new product contains improvements over older formulations, it cannot be said to be irrational *but for* its consequences on competition since it is commercially reasonable to offer better products. Second, there is nothing extrinsically wrong with offering new products, and such introductions violate no other law. As Defendants' Opening Brief notes (at pp. 9-11), the Section 2 standard in the product innovation context leads to a simple rule: If the new product offers any improvements over the old form, then the introduction is legal. *See* IIIA Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application*, ¶ 776d at 258 (2d ed. 2000 & 2005 Supp.) (no liability unless "the innovator knew before introducing the improvement into the market that it was *absolutely no better* than the prior version, and that the *only* purpose of the innovation was to eliminate the complementary product of a rival") (emphasis added).

There can be no dispute that Plaintiffs are attempting to have this Court condemn the introduction of new products by an alleged monopolist in the same market claimed to be monopolized. Plaintiffs allege that Abbott and Fournier are monopolists in the fenofibrate

market and that Teva and Impax are direct or potential competitors. At bottom, Plaintiffs' complaint is that they are ineffective because their horizontal rivals keep introducing new products and as a result have remained one step ahead.[5] The antitrust laws are intended to encourage – not punish – innovation, and courts and commentators alike routinely reject antitrust claims based on the introduction of new products:

> A superior product often impairs the sales and profits of rival firms, and a dominant firm can increase its dominance by introducing better products. Nevertheless, product superiority is one of the objects of competition and cannot be wrongful, even for a monopolist. Indeed, no responsible commentator proposes to subordinate the public and consumer interest in better products to the preservation of less inventive rivals. . . . We may therefore accept as a premise that "building the better mousetrap" is per se lawful.

IIIA Areeda & Hovenkamp, *supra*, ¶ 781a. The reason for the antitrust laws' deference to innovation is the courts' recognition that innovation and the introduction of new products is the essence of competition.[6] If a company introduces a product that consumers prefer, its rivals will be less able to compete unless they bring out a better product. This does not violate the antitrust laws, which were designed to protect competition, not competitors. *See Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 273 (2d Cir. 1979) ("We must always be mindful lest the Sherman Act be invoked perversely in favor of those who seek protection from the rigors of competition"). Adoption of any other standard would chill innovation if an innovator can be second-guessed after the fact for introducing a better product. Handcuffing a monopolist only serves to lessen the benefits of innovative activity which redound to the welfare of all consumers.

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[5] *See, e.g.*, Teva Opp. at 3-4; Impax Counterclaims, ¶¶ 119, 130.

[6] *See, e.g., Foremost Pro Color, Inc. v. Eastman Kodak Co.*, 703 F.2d 534, 543-45 (9th Cir. 1983) ("Kodak need not have constricted its product development so as to facilitate the sales of rival products") (internal quotations omitted), *overruled on other grounds by Hasbrouck v. Texaco, Inc.*, 842 F.2d 1034 (9th Cir. 1987); *David L. Aldridge Co. v. Microsoft Corp.*, 995 F. Supp. 728, 753 (S.D. Tex. 1998) ("even monopolists may improve their products").

B. The Cases Plaintiffs Cite In Support Of Their Various Legal Theories Are Inapposite.

The cases plaintiffs cite are readily distinguishable. First, many of those cases do not involve new product introduction, which courts and commentators are particularly and justifiably reluctant to discourage through imposition of antitrust liability. Second, to the extent the Plaintiffs' cases involve new product introduction, the issue arises in the context of a company using its monopoly power in one market to introduce a product for the purpose of distorting competition in an entirely different market. In such circumstances, a court must evaluate the new product introduction in the first market against the distortion of competition in the second market. No such balancing is sensible where, as here, the new product introduction does not adversely affect any other product market.[7]

Plaintiffs cite, *inter alia*, *In re IBM Peripheral EDP Devices Antitrust Litig.*, 481 F. Supp. 965 (N.D. Cal. 1979), *aff'd sub nom. Transamerica Computer Co. v. IBM Corp.*, 698 F.2d 1377 (9th Cir. 1983), and *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340 (Fed. Cir. 1998) for the proposition that Defendants' introduction of new products violated the Sherman Act. Plaintiffs' reliance on these cases is misplaced.

These cases involved conduct by companies with monopoly power in one market that also offer a second product in a related but competitive market. In each case, the monopolist attempted to leverage its power into that complementary market to favor its product offerings in that competitive market, typically through engineering physical incompatibility between related

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[7] Some Plaintiffs argue that Abbott and Fournier acted unlawfully in allegedly reducing consumer choice by discontinuing their older products. *See* Teva Opp. at 12. This argument fails for two reasons. First, it is black letter law that any competitor, even a monopolist, can choose which products to sell and not to sell. *See Berkey*, 603 F.2d at 286 ("any firm, even a monopolist, may generally bring its products to market whenever and however it chooses"). Second, Teva does sell versions of the discontinued TriCor 200 mg capsule and 160 mg tablet, so consumers do in fact have the ability to choose the older versions. *See generally* Teva Counterclaims, ¶¶ 59, 68.

products (*e.g.*, in *C.R. Bard,* the defendant changed the physical design of the biopsy gun (the first product market) to disadvantage other manufacturers of biopsy needles (the second product market) for the purpose of gaining an advantage in that second market). In effect, the plaintiffs in those cases were simply asking the court to let them compete on the merits in the second market. In contrast to those cases cited by Plaintiffs, Teva and Impax are complaining that Defendants' introduction of new products made it more difficult for them to compete in that very same market.

Plaintiffs' reliance on *C.R. Bard* and *Multistate Legal Studies, Inc. v. Harcourt Brace Jovanovisch Legal and Professional Publications, Inc.*, 63 F.3d 1540 (10th Cir. 1995), is also misplaced. *C.R. Bard* was also a monopoly leveraging case where the defendant used its market power in one market to improperly gain a competitive advantage in a second market. Moreover, its application beyond its particular facts is limited by a procedural quirk perhaps best summed up by Judge Gajarsa in his concurrence denying rehearing en banc:

> [T]he patent bar may, at first glance, be alarmed that the majority opinion opens the floodgates with respect to a new antitrust cause of action. However, it is important for the bar to note that the *only* argument Bard made on appeal regarding the antitrust violation was directed to the sufficiency of the evidence on this issue. Bard did not argue to this court that modification of a patented product within the scope of the claims by a patentee, cannot, as a matter of law, constitute an antitrust violation. Nor did Bard challenge the jury instructions. . . .
>
> Consequently, this case does not establish or endorse a new antitrust theory. The majority opinion turns solely on Bard's argument regarding the sufficiency of the evidence and its failure to challenge the propriety of the jury instructions.

C.R. Bard, Inc. v. M3 Sys., Inc., 161 F.3d 1380, 1381 (Fed. Cir. 1998) (emphasis in original).

Harcourt was not a product innovation case, but was instead a tying case where the defendant simply offered two separate products together without any change in their form. It

also did not reject Areeda and Hovenkamp, as Plaintiffs contend (Pacificare Opp. at 15). Instead, after acknowledging the deference to innovation urged by Areeda and Hovenkamp and recognizing the "difficulties and dangers" of inquiring into a defendant's intent, the *Harcourt* court simply concluded that its "degree of deference to product designers is reduced" when the claimed product improvement constitutes only a marketing change rather than a physical change to the product. 63 F.3d at 1552 n.10.

Among the Plaintiffs, only Pacificare acknowledges that this is a single market product innovation case. *See* Pacificare Opp. at 16-19. However, Pacificare fails to cite a single case in support of its view that imposition of liability in a single market case should be easier than in a leveraging case. The one case Pacificare does cite is *Harcourt*, which, as described above, is inapposite because it evaluated a tie between two separate products where there is no change whatsoever in the form of the two products. Pacificare also purports to cite Areeda and Hovenkamp for the proposition that per se legality for new products is inappropriate when the defendant has a substantially dominant position. *See* Pacificare Opp. at 18. This citation is unavailing. First, the example discussed in the treatise is a two-market example – one of a camera manufacturer designing a new camera to disadvantage competing film makers. Second, and more importantly, in the same paragraph cited by Pacificare, Areeda and Hovenkamp restate the test advocated by Defendants. Areeda & Hovenkamp, *supra*, ¶ 776a ("Even here, however, we would recognize antitrust liability only for innovations that were *clearly not superior* to the older technology, measured by an *ex ante* test.") (emphasis added).

C. The Legal Theories Advanced By Plaintiffs Are Similarly Inapposite.

Plaintiffs have combed the antitrust literature and have offered a number of potential tests that they argue should be applied to evaluate whether Abbott's and Fournier's

market conduct violates the Sherman Act, including a "rule of reason" test, a "profit sacrifice" test and a "purpose" test. None of these "tests" make sense here.

1. The Rule of Reason Balancing Test Is Inapplicable.

Plaintiffs cite *United States v. Microsoft Corp.*, 253 F.3d 34 (D.C. Cir. 2001) (*en banc per curiam*), *LePage's Inc. v. 3M*, 324 F.3d 141 (3d Cir. 2003), *cert. denied*, 542 U.S. 953 (2004), and *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181 (3d Cir. 2005), in support of their argument that this Court should employ a "rule of reason" balancing approach to the innovations at issue in this case. *See, e.g.*, Teva Opp. at 21, 24-25; Directs Opp. at 23-25. The facts and legal theories of these cases are significantly different and make clear that such an approach is not appropriate in this case.

Microsoft concerned a tying claim involving two distinct markets: the operating system and the browser markets. At issue in that case was Microsoft's leveraging of its operating system monopoly to contractually force original equipment manufacturers to reject rival browsers. *Microsoft*, 253 F.3d at 58, 60-67. *LePage's* centered on allegations that defendant 3M used a bundled rebate scheme and exclusive dealing arrangements to leverage its market power in Scotch tape, Post-It brand note paper, and other products into the market for private label transparent tape. *LePage's*, 324 F.3d at 145, 154-159. *Dentsply* had nothing to do with new product introduction and instead involved an exclusive dealing policy imposed by Dentsply, the dominant provider of artificial teeth, on its dealers whereby the dealers would be terminated if they did business with one of Dentsply's rivals. 399 F.3d at 191-96.

The cases and theories cited by Plaintiffs and described above do not address product introduction in single market antitrust cases. The defendants in those cases were not

introducing new products that made it more difficult for their rivals in that market to compete.[8] Asking a court to weigh, in a single market, the procompetitive value of any innovation against its effect on the competitors would be both unworkable and a distortion of the goals of the antitrust laws in promoting innovation. The use of a weighing analysis in this context would chill innovation and doom a company when offering a new product with incremental improvements.

2. Plaintiffs' "Profit Sacrifice" Test Is Inapplicable.

Plaintiffs also urge the Court to adopt a "profit sacrifice" test to evaluate the lawfulness of Defendants' new product introductions. *See, e.g.*, Directs Opp. at 25-27. Plaintiffs cite a number of cases that they argue support use of this standard; however, none of these cases applied such a test in the context of new product development. This profit sacrifice test has most commonly been used in the context of analyzing predatory pricing claims, where a defendant is accused of selling its product below cost with the intention of driving its rivals from the market, after which it would raise its prices and recoup its losses. *See, e.g., Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 224 (1993) (finding defendants' predatory below-cost pricing illegal only where actual losses on product sales were recouped in the long term by later price increases).

A "profit sacrifice" test would be particularly ill-suited for use where the allegedly wrongful conduct is the introduction of a new product. Every company selling branded pharmaceuticals, or most other products for that matter, engages in extensive research and development in the hopes of bringing a newer or better product to market. In virtually every

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[8] Plaintiffs also cite *Harcourt* and *Caldera, Inc. v. Microsoft Corp.*, 72 F. Supp. 2d 1295 (D. Utah 1999), in further support of their argument that a Rule of Reason balancing approach should be applied to this case. Teva Opp. at 25-26; Directs Opp. at 24. These cases are similarly inapposite because both involve tying claims.

case, the innovation costs substantial money at the sacrifice of short-term profits. Were the Court to apply Plaintiffs' profit sacrifice test to innovation, no monopolist could conduct research and development in pursuit of better products. Under Plaintiffs' proposed test, courts would have to impose antitrust liability on a wide variety of procompetitive business conduct.

3. Plaintiffs' Proposed "Purpose Test" Is Inapplicable.

Finally, Plaintiffs alternatively argue for a test under which a valid antitrust claim has been pled "so long as a plaintiff alleges that the 'real reason' for the product change was an anticompetitive one." Pacificare Opp. at 14.[9] This is simply not the law.

Antitrust law focuses on the competitive implications of a defendant's conduct, not on a defendant's subjective intent. *See, e.g.*, *Olympia Equip. Leasing Co. v. W. Union Tel. Co.*, 797 F.2d 370, 379 (7th Cir. 1986) ("if conduct is not objectively anticompetitive the fact that it was motivated by hostility to competitors . . . is irrelevant"); *Ocean State Physicians Health Plan v. Blue Cross & Blue Shield*, 883 F.2d 1101, 1113 (1st Cir. 1989) ("desire to crush a competitor, standing alone, is insufficient to make out a violation of the antitrust laws"). If it factors into the analysis at all, subjective intent is limited to gauging the scope of the probable anticompetitive effect of defendants' conduct. *See Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 602 (1985) (explaining that subjective intent is relevant to the extent it shows that the conduct at issue may be fairly characterized as anticompetitive or predatory).

For example, when a company brings a patent action, its subjective intent is to eliminate competition. The antitrust laws do not, however, condemn such conduct based on that intent but rather evaluate the competitive implications in the round, including the procompetitive policy of incenting innovation by granting legal protection from competition through a patent.

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[9] Plaintiffs cite *C.R. Bard* and *Harcourt* in support of that proposition. *See, e.g.*, Pacificare Opp. at 13-16.

The same policy considerations support the protection of innovation, which the inventors also intend for the purpose of disadvantaging its competitors.

D. Plaintiffs Cite To The Wrong Section In *Hovenkamp* When Reference To The Proper Section Supports Defendants' Position.

As Abbott and Fournier set forth in their Opening Brief (at 9-11), courts and antitrust scholars are in agreement about the importance of promoting new product development and the need to ensure that the antitrust laws are not misapplied in a way that punishes or chills innovation. "A superior product often impairs the sales and profits of rival firms, and a dominant firm can increase its dominance by introducing better products. Nevertheless, product superiority is one of the objects of competition and cannot be wrongful, even for a monopolist." IIIA Areeda & Hovenkamp, *supra*, ¶ 781a.

Plaintiffs claim that Abbott and Fournier have cited outdated and superseded commentaries from antitrust scholars, and specifically state that Professor Hovenkamp has "subsequently revised his proposed test" from that referenced in Defendants' Opening Brief. *See, e.g.*, Directs Opp. at 28. Plaintiffs are wrong on both counts. First, the Areeda and Hovenkamp antitrust treatise cited by Abbott and Fournier and in the paragraph above is periodically updated, including most recently in 2005. The passage cited to by Defendants is in the current version of this respected treatise. Second, and more troubling, Plaintiffs have not only cited phrases from Hovenkamp's Intellectual Property and Antitrust treatise out of context, they have referred to the wrong section while ignoring the one on point given the allegations in this litigation.

As discussed above, Plaintiffs do not allege that Abbott and Fournier are vertically integrated firms that are seeking to alter the relationship between two or more complementary product markets. Yet the section in the Hovenkamp treatise cited at length by

Plaintiffs – Section 12.3 – addresses exactly that issue. In fact, Section 12.3 is entitled "Interface Connections and Vertical Integration." The opening sentence of the subsection from which Plaintiffs have excerpted several quotations – Subsection 12.3e – reads: "Where a vertically integrated monopolist's technological change has altered the relationship between two or more complementary goods markets, reducing competition in the market the defendant does not currently control, the technological change might be thought to constitute anticompetitive conduct sufficient to support a section 2 claim." 1 Herbert Hovenkamp *et al.*, *IP & Antitrust* § 12.3e at 12-19 (2002 & 2005 Supp.). Hovenkamp's analysis in the section of the treatise cited by Plaintiffs addresses the issue of a company leveraging its monopoly power in one market to gain a competitive advantage in a different market.

The immediately preceding section, however, which is not cited by Plaintiffs, is on point. Section 12.2, titled "Innovation as Such as Predatory Practice," discusses – and categorically dismisses – potential claims by a horizontal competitor that it has been disadvantaged by a rival's innovation.

> The most straightforward type of antitrust claim is also the easiest to dispose of. Rivals periodically complain that a competitor's innovation has driven them out of the market, or at least made it more difficult for them to compete, whether by making the plaintiff's products less attractive by comparison or by forcing the plaintiff to innovate in turn.

Id. at 12-4. Hovenkamp concludes that, under these circumstances, no antitrust violation has occurred.

> If a direct competitor complains that another company beat it in the marketplace by developing better products, the correct rule to apply is one of per se legality. Indeed, this principle is so firmly established that it is difficult to find modern cases that even make the claim in this stark a form.

Id. at 12-5 & n.7.

E. The New Tricor Products Represented Improvements Over Their Predecessors.

Plaintiffs claim they have pled that Defendants' new product introductions represented no improvement over the previously offered products, and contest Defendants' contention that their pleadings in fact concede that successive iterations of TriCor manifested product improvements. *See, e.g.*, Teva Opp. at 18 ("neither of the changed TriCor forms improve the prior forms of the product"). However, Plaintiffs' averments of non-improvement are starkly contradicted by other portions of Plaintiffs' pleadings, in which improvements were both explicitly and implicitly acknowledged. Such averments therefore need not be unquestionably accepted as true. *See, e.g., Schuylkill Energy Res. v. Pa. Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997) (upholding dismissal of antitrust complaint on the basis that plaintiff's conclusory assertion that it was a competitor of the defendant was "belied by both the remaining factual allegations and the law" where plaintiff had elsewhere in its pleadings conceded it was a supplier, and hence not a competitor, of defendant); *Response Oncology v. MetraHealth Ins. Co.*, 978 F. Supp. 1052, 1058 (S.D. Fla. 1997) ("Courts must liberally construe and accept as true allegations of fact in the complaint and inferences reasonably deductible therefrom, but need not accept factual claims that are internally inconsistent.").[10]

The Court can take notice of the FDA-approved product labels (attached as Exhibit 2 to Defendants' Opening Brief)[11] which make clear that the newer dosages were not

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[10] *See also N. Ind. Gun & Outdoor Shows, Inc. v. City of S. Bend*, 163 F.3d 449, 454 (7th Cir. 1998) (holding a court is "not obliged to ignore any facts set forth in the complaint that undermine the plaintiff's claim") (citation omitted); Fed. R. Civ. P. 8(f) (requiring pleadings to "be so construed as to do substantial justice").

[11] As noted in our Opening Brief (at 6), since Teva introduced selected parts of the product labels in its Counterclaims, this Court may consider the *entire* labels, which portray a far different picture than the one Teva attempts to draw through selective disclosure. *See Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993); *In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1331 (3d Cir. 2002) (affirming dismissal where district court took judicial notice of documents referenced by or that were otherwise relevant to plaintiff's complaint).

merely cosmetic changes. For instance, the first page of each label makes clear that even if the active ingredient remains the same, the formula for the product has changed, and different ingredients are used.

Plaintiff's bald assertions of non-improvement do not comport with the facts averred in the pleadings. Plaintiffs admit that unlike the capsules and prior form of tablets, the 48 mg and 145 mg TriCor NFE tablets are not required to be taken with food. Teva Counterclaims, ¶ 98; Impax Counterclaims, ¶ 59. Moreover, Plaintiffs clearly acknowledge that, for at least a third of the patients taking TriCor, the NFE tablets represent an improvement. Teva Counterclaims, ¶ 98. Plaintiffs also acknowledge that the 160 mg "tablets had an additional indication for [an HDL effect], while TriCor capsules had not been approved for HDL treatment."[12] Teva Counterclaims, ¶ 71; *see also* Impax Counterclaims, ¶ 33.

Plaintiffs also explicitly acknowledge successive lowering of dosages with the introduction of new TriCor products, although they characterize the change in dosages as little more than cosmetic changes. *See, e.g.*, Teva Counterclaims, ¶ 70-71; Impax Counterclaims, ¶ 58; Walgreen Amended Compl., ¶ 51.

Importantly, to the extent any of Plaintiffs' factual pleadings are at odds with its exhibits (including, *inter alia*, the product labels), the exhibits control. For example, the court in *Hoff Supply Co. v. Allen-Bradley Co.*, 768 F. Supp. 132 (M.D. Pa. 1991), observed that the clear language of the contract forming the substance of the litigated dispute, attached to the plaintiff's pleading, undermined plaintiff's contrary assertions. The court held that "in the event of an

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[12] Plaintiffs claim that this HDL improvement should be ignored because Defendants could have chosen to introduce this benefit in connection with a capsule product. As noted in Defendants' Opening Brief, this argument flies in the face of well-established precedent that even a monopolist is free to choose the time and manner of its new product introductions. *See Berkey*, 603 F.2d at 286 ("any firm, even a monopolist, may generally bring its products to market whenever and however it chooses").

inconsistency between averments in the complaint and the actual provisions of the agreements, the agreements will prevail." *Id.* at 134 n.3; *see also ALA, Inc. v. CCAIR, Inc.*, 29 F.3d 855, 859 n.8 (3d Cir. 1994) ("Where there is a disparity between a written instrument annexed to a pleading and an allegation in the pleading based thereon, the written instrument will control."); 2 James Wm. Moore *et al.*, *Moore's Federal Practice: Civil 3d* § 10.05 [6] at 10-36 (2005) ("in the case of a conflict between the exhibit and the pleading, courts normally find that the exhibit controls").

Given the information contained on product labels, as well as in Plaintiffs' averments, it is clear in each case that Defendants' newer products were improvements over the previous versions.[13] Because these allegations are either within Plaintiffs' pleadings or can be judicially noticed at this stage of the proceedings, Plaintiffs' product introduction claims should be dismissed.

III. PLAINTIFFS' ALLEGATIONS WITH RESPECT TO ABBOTT'S AND FOURNIER'S LITIGATION CONDUCT FAIL TO STATE A CLAIM.

Plaintiffs collectively make three basic "wrongful litigation" allegations. First, all Plaintiffs allege that the Tablet Litigations were objectively baseless because Defendants "knew" that the Stamm patents would later be rendered unenforceable under the inequitable conduct doctrine. Only with respect to one patent, the '881, do Plaintiffs allege a *Walker Process* violation, the case in which the Supreme Court articulated the standard for assessing antitrust

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[13] Plaintiff's alternative request for leave to replead (Teva Opp. at 19 n.8) is improper and should be denied. "[A] bare request in an opposition to a motion to dismiss – without any indication of the particular grounds on which amendment is sought . . . does not constitute a motion within the contemplation of Rule 15(a)." *In re NAHC*, 306 F.3d at 1332 (quoting *Confederate Mem'l Ass'n v. Hines*, 995 F.2d 295, 299 (D.C. Cir. 1993)). Moreover, because the labels make clear that the new products represented improvements over their predecessors, any amendment would be futile. *Id.* at 1331-32 (affirming denial of leave to replead where there was no basis to believe any additional facts or arguments could be raised to defeat the motion to dismiss).

liability in the patent procurement process. Second, without regard to the propriety of procurement of the tablet patents, all Plaintiffs allege the prosecution of the Tablet Litigations before this Court was objectively baseless. Third, the Directs allege that Defendants' prosecution of the Capsule Litigation years ago was objectively baseless.

Each of these sets of allegations can be evaluated independently and, under such scrutiny, all are lacking in merit. First, it is well-settled law that the inequitable conduct doctrine is a patent defense and cannot support a finding of antitrust liability. Plaintiffs' suggested use of the inequitable conduct doctrine to show that Defendants' later prosecution of the patent cases is objectively baseless is a blatant attempt to bypass the Supreme Court's *Walker Process* requirements of what must be alleged to make an antitrust claim in the context of patent procurement. For the one *Walker Process* claim that the Plaintiffs did allege (the '881 patent claim), there is no antitrust injury since the Plaintiffs were lawfully excluded from the market through the proper application of the 30-month stay in connection with the prosecution of the infringement claim on the '405 patent. Second, once the patent procurement issues are properly set aside, this Court can determine on the record before it that the prosecution of the Tablet Litigations was not objectively baseless, since a number of the claims survived summary judgment and the case was set for trial. Finally, the Directs' attempt to resurrect the Capsule Litigations should also be dismissed.

A. Plaintiffs' Patent Procurement Allegations Fail.

In *Walker Process Equipment, Inc. v. Food Machinery and Chemical Corp.*, 382 U.S. 172 (1965), the Supreme Court held that patent litigation could establish antitrust liability only if the patent-at-issue was procured by "intentional fraud." *Id.* at 176. For less egregious behavior, such as inequitable conduct and other "technical frauds," the patent may be rendered unenforceable but the patentee remains immune to antitrust suits. *Id.* at 177. As Justice Harlan

explained, by requiring intentional fraud the Court carefully balanced "the differing policies of the patent and antitrust laws" to ensure that treble damages antitrust actions would not "chill the [promotion and] disclosure of inventions." *Id.* at 179-80 (Harlan, J. concurring).

Professional Real Estate, Inv., Inc. v. Columbia Pictures Industries, 508 U.S. 49 (1993) ("*PRE*"), decided years later, did not involve sham patent litigation and does not limit *Walker Process*. Citing *Walker Process*, the Supreme Court in *PRE* specifically refrained from setting forth a rule applying its sham litigation standard in the context of fraud or other misrepresentations. *See id.* at 61 n.6. The Supreme Court left open how to reconcile the two decisions, but commentators have noted that the two decisions can be read quite consistently by viewing the requisite fraud on the PTO as the core of an objectively baseless litigation. *See, e.g.*, James B. Kobak, Jr., *The Doctrine That Will Not Die: Nobelpharma, Walker Process, and the Patent-Antitrust Counterclaim*, 13 Antitrust 47 (1998) (knowing enforcement of fraudulently obtained patent is objectively baseless); S.W. O'Donnell, *Unified Theory of Antitrust Counterclaims in Patent Litigation*, 9 Va. J.L. & Tech. 8 (2004) ("*Walker Process* fraud . . . is . . . at its core . . . sham litigation"). In this manner, *Walker Process* fraud is a subset of *PRE* objectively baseless claims, not a separate cause of action.

Plaintiffs attempt to end-run the *Walker Process* requirements and use an inequitable conduct patent defense as a basis for asserting an antitrust violation. Plaintiffs argue that their allegations of inequitable conduct before the patent office need only meet *PRE*'s "objectively baseless" test, and cite *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1071 (Fed. Cir. 1998), for the proposition that *PRE*'s objectively baseless test and *Walker Process* are independent exceptions to *Noerr-Pennington*. *See, e.g.*, Teva Opp. at 47. Plaintiffs' reliance on *Nobelpharma* is misplaced. The central holding in *Nobelpharma* is the express recognition that the inequitable conduct doctrine is limited to a defense against a patent

prosecution and that only the higher showing of fraud under *Walker Process* is sufficient to allow the prosecution of a patent to expose the litigant to antitrust liability. *Id.* at 1069 (citing Justice Harlan); *see also id.* at 1070 ("Inequitable conduct is thus an equitable defense in a patent infringement action and serves as a shield, while a more serious finding of fraud potentially exposes a patentee to antitrust liability and thus serves as a sword.").

Plaintiffs' citation to dictum from *Nobelpharma* that *Walker Process* and *PRE* are separate causes of action is unpersuasive in the context of evaluating claims of improper patent procurement. At the outset, the dictum cited by Plaintiffs is related to the Federal Circuit's upholding of the district court's finding of a *Walker Process* violation without the need to resort to a separate analysis of the same claims under *PRE*. The dictum's acknowledgement that *PRE* can provide an independent cause of action for certain matters is undoubtedly correct in the right context; for example, in a case where a patent is valid but the patent holder brings suit knowing that there is no objective basis for infringement, a *PRE* claim may lie where no *Walker Process* claim would. But *Nobelpharma*'s notation of this point does not change its holding that the *Walker Process* standards govern the treatment of antitrust liability in the context of patent procurement. Thus, the dictum in *Nobelpharma* is nothing more than an acknowledgement that both the *PRE* and *Walker Process* doctrines can deprive a defendant of antitrust immunity in their respective contexts.

In *Cheminor Drugs, Ltd. v. Ethyl Corp.*, 168 F.3d 119 (3d Cir. 1999), a case decided after *Nobelpharma*, the plaintiff argued both that *Noerr-Pennington* immunity does not apply at all to petitions containing misrepresentations and that the misrepresentations can make a petition objectively baseless. The Third Circuit rejected this theory, stating, "[w]e decline to carve out a new exception to the broad immunity that *Noerr-Pennington* provides." *Id.* at 123. The *Cheminor* court noted that, as a general matter, misrepresentations that do not affect the very

core of the litigant's case are immunized under *Noerr-Pennington*. *Id.* at 124. With respect to misrepresentations before the patent office specifically, the *Cheminor* court reiterated that *Walker Process* fraud remains the required standard: "Moreover, misrepresentations made to procure a patent must rise to the level of fraud in order to cause a patent infringement action to fail – unethical behavior alone is insufficient." *Id.* (citing *Nobelpharma* and *Walker Process*). Thus, *Cheminor's* view of the *Noerr-Pennington* immunity as a single coherent doctrine is further support for the proposition that *Walker Process* and *PRE* are not separate and distinct exceptions for conduct before the PTO.

Because Plaintiffs' sham litigation claims related to patent procurement are predicated only on alleged inequitable conduct (with the exception of the '881 patent), and not the knowing and willful fraud required by *Walker Process*, they must be dismissed for failure to state a claim upon which relief may be granted. And as noted in Defendants' Opening Brief, Plaintiffs' sole *Walker Process* claim – with respect to the '881 patent – fails for lack of antitrust injury since Teva was barred from entering the market by the proper application of the 30-month stay with respect to the '405 patent.[14] Since at least claim 6 of the '405 patent was set for trial and there is no cognizable allegation that that patent was wrongfully procured, Teva's exclusion from the market resulted from operation of law and not wrongful conduct by Defendants.

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[14] Teva and Impax allege antitrust injury arising from having to pay attorneys' fees to defend the '881 infringement action, yet offer no indication as to how or why these fees are distinguishable from fees Teva and Impax were already paying to defend on the other patents. Hence this argument for antitrust injury fails by extension of the same logic fatal to Plaintiffs' broader injury claim. In any event, even if the Court were to find such relatively nominal injury, that injury would not extend to Direct and Indirect Purchaser Plaintiffs who were not parties to the '881 action.

B. This Court's Summary Judgment Decision Demonstrates That Defendants' Tablet Litigations Were Not Objectively Baseless.

Plaintiffs argue that this Court did not determine, in connection with the summary judgment proceedings or otherwise, that the litigations were "objectively reasonable." *See, e.g.*, Teva Opp. at 40-42. As our Opening Brief demonstrated (at 19-20 & n.18), this Court rejected eight of the nine summary judgment motions filed by Teva and Impax, either in whole or in part, ruled favorably for Defendants on six of eight claim construction determinations, and set for trial several claims with respect to both the '881 and the '405 patents. That these claims survived summary judgment, based upon conflicting evidence and expert testimony, validates Defendants' objective reasonableness in bringing and maintaining the litigation.

The record of the Tablet Litigations makes clear that Defendants initiated these suits with probable cause, the existence of which "irrefutably demonstrates that an antitrust plaintiff has not proved the objective prong of the sham exception and that the defendant is accordingly entitled to *Noerr* immunity." *PRE*, 508 U.S. at 63.

C. Defendants Did Not Conduct The Capsule Litigations In Bad Faith.

Notably, Teva and Impax, the actual parties to the Capsule Litigations, do not allege that Defendants conducted that litigation in bad faith or that it was otherwise a sham. This allegation is raised only by the Direct Purchaser Plaintiffs, in support of which these Plaintiffs point only to the summary judgment decision and appeal as support for the fact that Defendants allegedly conducted the Capsule Litigations in bad faith. *See, e.g.*, Directs Opp. at 35-38; Pacificare Opp. at 30-32. Review of those decisions does not support Plaintiffs' argument.

The outcome of the Capsule Litigation turned on the district court's construction of the term "co-micronized," which, at the time of the litigation, had an undisputed plain meaning to one of ordinary skill in the relevant art: micronized with or together. *See Abbott Labs. v. Novopharm Ltd.*, Nos. 00 C 2141, 5094, and 1914, 2002 WL 433584, at *6 (N.D. Ill.

Mar. 20, 2002), *aff'd*, 323 F.3d 1324 (Fed. Cir. 2003) (attached hereto as Exhibit 3). The district court acknowledged that "a court should give a claim term the full range of its ordinary meaning as understood by one of ordinary skill in the relevant art." *Id.* at *4. Nevertheless, the court read a limitation into the independent claims based on the language in the claims, the description, and the prosecution history, which only applied the term "co-micronization" in connection with fenofibrate and a "solid surfactant," and ultimately concluded that "co-micronization" of fenofibrate with a solid surfactant is properly "construed to mean that fenofibrate and a solid surfactant have been micronized together *in the absence of other excipients*." *Id.* at *7 (emphasis added).

The Federal Circuit affirmed the district court's construction on appeal, but nevertheless made clear that had the term not been limited by the patent specification and instead been given its ordinary meaning, it "might well agree with the appellants that the term could simply mean 'micronized with or together' and would not necessarily exclude the presence of ingredients not specifically recited in the claim." *See Abbott Labs. v. Novopharm Ltd.*, 323 F.3d 1324, 1330 (Fed. Cir. 2003). The Federal Circuit also agreed with Defendants that the district court had "erred in its doctrine of equivalents analysis" but concluded that such error was harmless because Novopharm's micronization process did not use a solid surfactant. *Id.* at 1331. Though Defendants ultimately did not prevail in the litigation, these court decisions demonstrate that the Capsule Litigations were not objectively baseless or otherwise conducted in bad faith. *See Covad Commc'n Co. v. Bell Atl. Corp.*, 398 F.3d 666, 677 (D.C. Cir. 2005) (infringement action lost on summary judgment was not a sham because patentee "advanced reasonable arguments that [the Federal Circuit and district court] went to some lengths to reject"); *USA Video Tech. Corp. v. Movielink, LLC*, No. Civ. A. 03 368 KAJ, 2005 WL 3418407, at *5 (D.

Del. Dec. 13, 2005) ("The fact that an argument fails does not make it baseless") (attached hereto as Exhibit 4).

Teva and Impax, the actual parties to the Capsule Litigation, did not then and do not now challenge the propriety of that litigation, and are now barred from raising any such claims. Because the district court and Federal Circuit decisions do not even implicitly conclude that the Capsule Litigation was frivolous or instituted in bad faith, and the actual parties to that litigation did not then and do not now even suggest that Defendants' prosecution of that litigation was objectively baseless, this Court should reject the Direct Purchaser Plaintiffs' post-hoc analysis and collateral attack of those prior proceedings, and dismiss this claim.

IV. PLAINTIFFS' "OVERALL SCHEME" ALLEGATIONS FAIL TO STATE A CLAIM.

Some Plaintiffs argue that a monopolization claim can stand based solely on allegations that Defendants' conduct constituted an "overall scheme" to monopolize, even if none of the predicate conduct is wrongful or exclusionary. *See, e.g.*, Directs Opp. at 43. Yet, Plaintiffs fail to cite a single case in which there was an absence of wrongful conduct.

A. Immunized Litigation Conduct Cannot Be Part Of An Overall Scheme.

Plaintiffs argue that *Noerr* immunized conduct can constitute part of an overall unlawful scheme. This argument guts the protection intended to be provided under the *Noerr-Pennington* doctrine. *See United Mine Workers of Am. v. Pennington*, 381 U.S. 657, 670 (1965) (holding that protected petitioning conduct cannot form the basis for antitrust liability "either standing alone or as part of a broader scheme.").

Plaintiffs cite *United States v. Singer Manufacturing Co.*, 374 U.S. 174 (1963), *California Motor Transport. Co. v. Trucking Unlimited*, 404 U.S. 508 (1974), and *Clipper Exxpress v. Rocky Mountain Motor Tariff Bureau, Inc.*, 690 F.2d 1240 (9th Cir. 1980), as direct

authority for their proposition. *See, e.g.*, Pacificare Opp. at 28; Teva Opp. at 35. None of these cases actually support Plaintiffs' argument. *Singer* was decided two years before *Pennington*, and *Trucking Unlimited* and *Clipper Exxpress* each imposed antitrust liability not on the basis that protected conduct formed part of an overall scheme, but instead because sham petitioning stripped defendants of their *Noerr* immunity. *Trucking Unlimited*, 404 U.S. at 516 (the "allegations come within the 'sham' exception in the Noerr case"); *Clipper Exxpress*, 690 F.2d at 1253 (the allegation that defendants' petitioning conduct was instituted only to delay competitive action and not to influence government action "fall[s] within the sham exception as a matter of law").

The remaining cases Plaintiffs cite are similarly unavailing. *See* Teva Opp. at 34-36; Pacificare Opp. at 28-29; Directs Opp. at 35 n.16. In *Atari Games Corp. v. Nintendo of America, Inc.* 897 F.2d 1572 (Fed. Cir. 1990), the Federal Circuit did not consider the issue, but instead reversed a preliminary injunction entered against defendant in part because the licensing restrictions about which plaintiffs complained were "not, as a matter of law, antitrust violations." *Id.* at 1578. Plaintiffs apparently cite *Atari* for its reference to *Kobe, Inc. v. Dempsey Pump Co.*, 198 F.2d 416 (10th Cir. 1952). *Kobe*, decided before *Pennington*, is less an overall scheme case than it is a garden-variety patent pooling case for which prior Supreme Court precedent had already established Section 2 liability. 198 F.2d at 422. Thus, the non-frivolous patent litigation at issue in that case constituted the necessary element that made actionable the patent-pooling scheme. *Id.* 424-25. The court in *ID Security Systems Canada, Inc. v. Checkpoint Systems, Inc.*, 249 F. Supp. 2d 622 (E.D. Pa. 2003), granted judgment for defendant notwithstanding the jury's antitrust verdict, observing that no error resulted from admission of evidence against defendant pursuant to an *Atari/Kobe* overall scheme theory. *Handgards, Inc. v. Ethicon, Inc.*, 601 F.2d 986 (9th Cir. 1979), explicitly rejected application of a *Kobe* overall scheme theory and instead

concluded that plaintiff alleged only a bad faith litigation claim. *Id.* at 994. Similar to *Trucking Unlimited* and *Clipper Exxpress*, the court in *Alexander v. Associated Milk Producers, Inc.*, 687 F.2d 1173 (8th Cir. 1982), concluded that boycotts, even if aimed at hurting competition, were not sham petitioning and, as a result, were "not actionable alone or as an element of a larger scheme." *Id.* at 1195. *Rockbit Industries U.S.A., Inc. v. Baker Hughes, Inc.*, 802 F. Supp. 1544, 1548-49 (S.D. Tex. 1991), did not involve *Noerr-Pennington* immunity, but instead rejected plaintiff's argument that an overall scheme theory provided plaintiff standing to challenge the price-fixing scheme at issue in that case.

In sum, none of the authorities Plaintiffs cite refute the proposition established by *Pennington* and advanced by Defendants in their Opening Brief that protected petitioning activity cannot form the basis for antitrust liability "either alone or as part of a broader scheme." Without the alleged litigation misconduct, Plaintiffs allegations of an overall scheme fail.

B. An Allegation Of An Overall Scheme Without Any Wrongful Conduct Fails To State A Cognizable Antitrust Claim.

Plaintiffs appear to argue that a scheme involving separate elements of legitimate conduct can, in the aggregate, support a finding of an illegal scheme. Yet, the cases cited by Plaintiffs involve wrongful predicate conduct. *See* Teva Opp. at 37-39; Pacificare Opp. at 25-27; Directs Opp. at 41-43.[15] Unlike the facts in the cases cited by Plaintiffs, the allegations made

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[15] *See Cont'l Ore v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 695 (1962) (involving allegations that defendant cut off supplies of raw materials to plaintiff and interfered with certain contracts); *Aspen Skiing Co* , 472 U.S. at 607-08 (involving refusal to deal allegations); *Am. Tobacco Co. v. United States*, 328 U.S. at 800 (involving refusal to deal and price fixing allegations); *LePage's*, 324 F.3d at 145, 154-159 (involving allegations of exclusive dealing and bundling); *Dentsply*, 399 F.3d at 191-96 (involving allegations of exclusive dealing); *Atari*, 897 F.2d at 1575, 1577 (reversing where plaintiffs' allegations of improper licensing restrictions did not violate antitrust law); *Biovail Corp. Int'l v. Hoechst AG*, 49 F. Supp. 2d 750, 759 (D.N.J. 1999) (involving allegations that plaintiff repudiated an FTC decree and paid generic manufacturer to delay marketing a competing drug); *SmithKline Beecham Corp. v. Apotex Corp.*, 383 F. Supp. 2d 686, 694 (E.D. Pa. 2004) (involving allegations that defendants entered into a collusive settlement with one of plaintiff's rival generic drug manufacturers); *In re Remeron Antitrust Litig.*, 335 F. Supp. 2d 522, 530 (D.N.J. 2004) (involving allegations that defendant purposefully late listed its patent in

against Abbott and Fournier do not include tying arrangements, refusals to deal, exclusionary dealings, predatory pricing, price fixing, collusive patent infringement settlements, or false and misleading advertising. The only allegation is that Defendants made it more difficult – but not impossible – for the generics to compete.

Instead, the constituent elements of Plaintiffs' "overall scheme" involve either conduct that is specifically immunized from antitrust challenge under *Noerr-Pennington* or that is otherwise sanctioned by Hatch-Waxman as lawful and appropriate commercial conduct. *See, e.g.*, Opening Brief at 29-30. Plaintiffs cite the notion that a monopolist may not engage in certain actions that an ordinary commercial actor may do. Nonetheless, this does not mean that actions that are legal for the monopolist to do standing alone become illegal when done in the aggregate.

Indeed, if the Court were to hold that Plaintiffs could assert a claim for monopolization without requiring that any of Defendants' conduct actually be wrongful, competition could be stifled inadvertently because market actors would have no standard by which to judge their conduct. How could any company discern which conduct was legal and which conduct – if alleged to be part of an overall scheme – might thereby constitute a violation of the antitrust laws? The fact that such a standard is unworkable is not just a theoretical problem, but is a problem that may confront the Court in this litigation. Certain Plaintiffs in this litigation have asked the Court to grant injunctive relief prohibiting unspecified but allegedly

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the Orange Book in violation of federal regulations); *Cal. Energy Co. v. S. Cal. Edison Co.*, No. C 91-0319-JPV, 1992 WL 330263, at *1 (N.D. Cal. Sep. 22, 1992) (involving allegations of interference with third parties and publication of severely critical equity report) (attached hereto as Exhibit 5); *Anaheim v. S. Cal. Edison Co.*, 955 F.2d 1373, 1381 (9th Cir. 1992) (affirming judgment for defendant in case involving allegations that defendant denied plaintiff access to essential facilities); and *Caldera*, 72 F. Supp. 2d at 1297-1305 (D. Utah 1999) (involving allegations that defendant made false and misleading preannouncements to undercut the market for plaintiff's product). Plaintiffs also cite *Borden, Inc. v. FTC*, 674 F.2d 498, 516 (6th Cir. 1982) (involving allegations of predatory pricing), *see* Directs' Opp. at 43-44, but that opinion was vacated by the Supreme Court. *See Borden, Inc. v. FTC*, 461 U.S. 940 (1983).

unlawful actions. If Plaintiffs were to prevail on a theory that Defendants' otherwise legal conduct could constitute an illegal overall scheme to monopolize the market, it is not at all clear how this Court could fashion appropriate injunctive relief. Would every aspect alleged to be part of the scheme be prohibited? If not every aspect, which specific aspects would be permitted and which would be prohibited? The practical difficulties of allowing an antitrust claim to stand on such a theory may explain why Plaintiffs have been unable to locate a case to date where liability was found under such a theory in the absence of such wrongful conduct, and highlights why the Court should not allow such a claim to proceed in this litigation.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that this Court dismiss Plaintiffs' complaints and counterclaims with prejudice as set forth in Defendants' proposed Order (attached hereto as Exhibit 6).

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